52. (Amended once) The polypeptide of claim 48, wherein one of said non-self IgE domains is an IgE CH2 domain, wherein one of said non-self IgE domains is an IgE CH4 domain, and wherein said self IgE CH3 domain is located between said IgE CH2 domain and said IgE CH4 domain.

53. (Amended) The polypeptide of claim 58, wherein one of said non-self IgE domains is an IgE CH2 domain.

54. (Amended once) The polypeptide of claim 58, wherein one of said non-self IgE domains is an IgE CH4 domain.

REMARKS

Claims 1, 2, 4-11, and 25-54 were rejected. Claims 1, 2 and 4-11 have been cancelled herein, and claims 25, 27, 30-33, 35, 38-41, 45-48, 50 and 52-54 have been amended herein. Thus, claims 25-54 are pending. Specifically, claims 25, 27, 30-33, 35, 38-41, 45-48, 50 and 52-54 have been amended to recite domains, as opposed to portions or regions. Support for these claim amendments can be found throughout Applicant's specification. For example, at page 17, line 17 to page 18, line 22, Applicant's specification describes immunogenic polypeptides that have domains. Thus, no new matter has been added. Applicant respectfully requests reconsideration and allowance of claims 25-54.

Non-enablement rejection under 35 U.S.C. § 112

The Examiner rejected claims 1, 2, 4-11 and 25-54 under 35 U.S.C. § 112, first paragraph, stating that:

> the specification, while being enabling for "an immunogenic polypeptide comprising a non-self IgE CH2 domain, a self IgE CH3 domain, and a non-self IgE CH4 domain" (claim 1), does not reasonably provide enablement for:
>
> (A) "An immungenic polypeptide comprising a self IgE portion and a nonself IgE portion, and wherein said self IgE portion comprises at least a portion of a CH3 domain of IgE" (claim 1),

(B) "An immunogenic polypeptide of clam 1 wherein the nonself portion comprises a first region and a second region, said self IgE portion being located between said first and second regions of said nonself IgE portion" (claim 5),

(C) "The immunogenic polypeptide of claim 5, wherein said first region comprises at least a portion of an IgE CH2 domain" (claim 6),

(D) "The immunogenic polypeptide of claim 5, wherein said first region comprises at least a portion of an IgE CH4 domain" (claim 7).

See OA at page 2, item 5.

Applicant respectfully disagrees. Applicant's specification fully enables the invention recited in original claims 1, 2, 4-11 and 25-54. For example, Applicant's specification adequately teaches ordinarily skilled artisans how to make and use immunogenic polypeptides having self and non-self portions, where the portions are entire domains or are parts of domains (see e.g., page 17, line 17 to page 18, line 22; and Figure 2a).

To further prosecution, however, claims 1, 2 and 4-11 have been cancelled. In addition, claims 25, 27, 30-33, 35, 38-41, 45-48, 50 and 52-54 have been amended to recite domains as opposed to regions or portions. As the Examiner indicated, immunogenic polypeptides comprising domains are enabled by Applicant's specification. Thus, Applicant respectfully requests that the rejection of claims 25-54 under 35 U.S.C. § 112 be withdrawn.

New matter rejection under 35 U.S.C. § 112

The Examiner rejected claims 1, 2, 4-11 and 33-40 under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. In particular, the Examiner asserts that the recitation of "consisting essentially of" in claims 1 and 33 is not supported by the specification, and therefore constitutes new matter. See OA at page 3, item 7.

Applicant respectfully disagrees. Applicant's specification fully supports the invention recited in claims 1, 2, 4-11 and 33-40. To further prosecution, however, claims 1, 2 and 4-11 have been cancelled. In addition, independent claim 33 has been amended to recite an immunogenic polypeptide comprising, *inter alia*, an N-terminal half of a self IgE CH3 domain. Applicant's specification fully supports amended claim 33. For example, support can be found

at page 18, lines 14 to 22, and in Figure 2 (see amino acid sequence of polypeptides containing the components: opossum CH2—rat N-term CH3—opossum C-term CH3—opossum CH4). Thus, no new matter has been added. Applicant therefore respectfully requests that the rejection of claims 33-40 under 35 U.S.C. § 112 be withdrawn.

Conclusion

In light of the above amendments and remarks, Applicant respectfully requests allowance of claims 25-54. For the Examiner's convenience, Applicant attaches a marked-up version of the changes made by the current amendment. Applicant also encloses a check for the Petition for Extension of Time fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: April 4, 2002

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Version with markings to show changes made

In the claims:

Claims 1, 2, and 4-11 have been cancelled. Claims 25, 27, 30-33, 35, 38-41, 45-48, 50, and 52-54 have been amended as follows:

25. (Amended once) An immunogenic polypeptide, comprising a self IgE [portion] CH3 domain and [a] one or more non-self IgE [portion] domains, wherein said immunogenic polypeptide is effective to induce an anti-self IgE response in a mammal, [wherein said self IgE portion comprises at least a portion of a CH3 domain of IgE,] and wherein said immunogenic polypeptide lacks a CH1 domain of IgE.

27. (Amended once) The immunogenic polypeptide of claim 26, wherein at least one of said non-self IgE [portion] domains comprises an IgE sequence present in a non-placental mammal.

30. (Amended once) The immunogenic polypeptide of claim 25, wherein one of said non-self IgE [portion comprises a first region and a second region, said self IgE portion being located between said first and second regions of said non-self IgE portion] domains is an IgE CH2 domain, wherein one of said non-self IgE domains is an IgE CH4 domain, and wherein said self IgE CH3 domain is located between said IgE CH2 domain and said IgE CH4 domain.

31. (Amended once) The immunogenic polypeptide of claim [30] 25, wherein one of said non-self IgE domains is [said first region comprises at least a portion of] an IgE CH2 domain.

32. (Amended once) The immunogenic polypeptide of claim [30] 25, wherein one of said non-self IgE domains is [said second region comprises at least a portion of] an IgE CH4 domain.

33. (Amended once) An immunogenic polypeptide, comprising [a self IgE portion and a] one or more non-self IgE [portion] domains, and an N-terminal half of a self IgE CH3 domain,

wherein said immunogenic polypeptide is effective to induce an anti-self IgE response in a mammal [, and wherein said self IgE portion consists essentially of an N-terminal portion of a CH3 domain of IgE].

35. (Amended once) The immunogenic polypeptide of claim 34, wherein at least one of said non-self IgE [portion] domains comprises an IgE sequence present in a non-placental mammal.

38. (Amended once) The immunogenic polypeptide of claim 33, wherein one of said non-self IgE [portion comprises a first region and a second region, said self IgE portion being located between said first and second regions of said non-self IgE portion] domains is an IgE CH2 domain, wherein one of said non-self IgE domains is an IgE CH4 domain, and wherein said N-terminal half of a self IgE CH3 domain is located between said IgE CH2 domain and said IgE CH4 domain.

39. (Amended once) The immunogenic polypeptide of claim [38] 33, wherein one of said non-self IgE domains is [said first region comprises at least a portion of] an IgE CH2 domain.

40. (Amended once) The immunogenic polypeptide of claim [38] 33, wherein one of said non-self IgE domains is [said second region comprises at least a portion of] an IgE CH4 domain.

41. (Amended once) An immunogenic polypeptide, comprising a self IgE [portion] domain and [a] one or more non-self IgE [portion] domains, wherein said immunogenic polypeptide is effective to induce an anti-self IgE response in a mammal, and wherein at least one of said non-self IgE [portion] domains comprises an IgE sequence present in a non-placental mammal.

45. (Amended once) The immunogenic polypeptide of claim 41, wherein one of said non-self IgE [portion comprises a first region and a second region, said self IgE portion being located between said first and second regions of said non-self IgE portion] domains is an IgE CH2 domain, wherein one of said non-self IgE domains is an IgE CH4 domain, and wherein said self IgE CH3 domain is located between said IgE CH2 domain and said IgE CH4 domain.

46. (Amended once) The immunogenic polypeptide of claim [45] 41, wherein one of said non-self IgE domains is [said first region comprises at least a portion of] an IgE CH2 domain.

47. (Amended once) The immunogenic polypeptide of claim [45] 41, wherein one of said non-self IgE domains is [said second region comprises at least a portion of] an IgE CH4 domain.

48. (Amended once) A polypeptide, comprising a self IgE [portion] CH3 domain and [a] one or more non-self IgE [portion] domains, wherein said polypeptide lacks light chain Ig sequences and is effective to induce an anti-self IgE response in a mammal [, wherein said self IgE portion comprises at least a portion of a CH3 domain of IgE].

50. (Amended once) The polypeptide of claim 49, wherein at least one of said non-self IgE [portion] domains comprises an IgE sequence present in a non-placental mammal.

52. (Amended once) The polypeptide of claim 48, wherein one of said non-self IgE [portion comprises a first region and a second region, said self IgE portion being located between said first and second regions of said non-self IgE portion] domains is an IgE CH2 domain, wherein one of said non-self IgE domains is an IgE CH4 domain, and wherein said self IgE CH3 domain is located between said IgE CH2 domain and said IgE CH4 domain.

53. (Amended) The polypeptide of claim [52] 58, wherein one of said non-self IgE domains is [said first region comprises at least a portion of] an IgE CH2 domain.

54. (Amended once) The polypeptide of claim [52] 58, wherein one of said non-self IgE domains is [said second region comprises at least a portion of] an IgE CH4 domain.